UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/410,336	10/01/1999	SUSAN LOVE	12.006011	6727

38732 7590 09/23/2004

CYTYC CORPORATION
85 SWANSON ROAD
BOXBOROUGH, MA 01719

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/410,336	LOVE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-48* is/are pending in the application.

4a) Of the above claim(s) *40-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed June 17, 2004 has been entered. Claims 1-16 have been canceled. Claims 33-48 have been added.

2. Claims 33-48 are pending in the application. Claims 40-48 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Claims 33-39 are pending in the application and are currently under prosecution.

Grounds of Objection and Rejection Withdrawn

4. Without acquiescing to Applicant's arguments, the grounds of rejection set forth in the previous Office action mailed December 31, 2003, have been withdrawn, since Applicant's amendment filed June 17, 2004, canceling all previously examined claims has rendered those grounds moot.

Response to Amendment

5. Applicant's arguments set forth in the amendment filed June 17, 2004, traversing the grounds of rejection of claims 1-16 under 35 USC § 103(a) set forth in the previous Office action, have been carefully considered but are moot in view of Applicant's cancellation of those claims and in further view of the new grounds of objection and rejection set forth below.

Election/Restrictions

6. Newly submitted claims 40-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

In the paper filed February 2, 2001, Applicant elected the invention of Group I, claims 1-16. Claims 1-8 (now canceled) were originally drawn to a method for identifying the location of premalignant or malignant breast cancer within a breast duct

or breast ductal network; and claims 9-16 (now canceled) were drawn to a method of determining the lymph node involvement in patients diagnosed with premalignant or malignant breast cancer. Similarly, newly added claims 33-36 are drawn to a method for identifying the location of a lesion (e.g., premalignant or malignant breast cancer) within a breast duct or breast ductal network. In contrast, newly added claims 40-48 are drawn to a method of staging a neoplastic breast lesion within a breast duct or breast ductal network. The inventions of claims 40-48 are distinct from the elected invention, because the objective of practicing the inventions of claims 40-48 differs from the objective of practicing the elected invention. Newly add claims 40-48 are drawn to a method for staging a neoplastic breast lesion comprising differentiating, for example, hyperplastic, atypical hyperplastic, and low-grade ductal carcinoma *in situ*, whereas the elected invention is drawn to a method for determining the location of a premalignant or malignant lesion without regard to the stage of the lesion. Because the objectives differ, a new and different search and new and different considerations would be necessary to examine the merit of newly added claims 40-48.

Because the search required for examination of the subject matter of newly added claims 40-48 and the search required for examination of the elected invention are not co-extensive in nature and scope, and also because the subject matter of the elected invention and the subject matter of newly added claims 40-48 have acquired a separate status in the art and are recognized as being divergent, restriction for examination purposes as indicated is deemed proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-48 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

7. Claim 37 is objected to because the claim recites, "[...] wherein said *target* agent comprises [...]" (italicized for emphasis). As claim 37 depends from claim 33, which

recites, [...] comprising a *targeting* agent coupled to [...]" (italicized for emphasis), the recitation of "target agent", as opposed to "targeting agent", in claim 37 is inconsistent with claim 33. Appropriate correction is required.

8. Claim 39 is objected to because the claim recites, "[...] said detection of said compound [...]". Although it is clear that the compound comprising the targeting agent coupled to the identifying agent is detected, claim 33 recites, "detecting the presence of said identifying agent", as opposed to "detecting the presence of said compound", so claim 39 should recite "[...] said detection of said identifying agent [...]". Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 33-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

Claims 33-39 are drawn to a method of identifying the location of *a lesion within a breast duct or breast ductal network*. In contrast, claim 1, as originally filed, was drawn to a method of identifying the location of premalignant or malignant **breast cancer** within a breast duct or breast ductal network. Furthermore, the specification discloses, for example, at page 5 (lines 28-30) that "[t]he present invention provides improved methods, systems, and kits for identification, diagnosis (including staging), and treatment of malignant and premalignant **lesions of the breast**" (emboldened for

emphasis). The specification, therefore, does not appear to provide proper and sufficient written support for the presently claimed method of identifying the location of *any lesion* in a breast duct or breast ductal network, and which is not limited a method of identifying a lesion of the breast (e.g., malignant or premalignant breast cancer).

In addition, claim 34 recites, "wherein delivering comprises *non-percutaneous* cannulation or catheterization of the breast duct" (italicized for emphasis). It does not appear that the specification, including the claims, as originally filed, provides expressive written support for the term "non-percutaneous". Furthermore, the specification does not clearly describe the disclosed methods of cannulation or catheterization as "non-percutaneous", since, for example, the specification does not appear to describe, compare, or contrast the disclosed methods to "percutaneous" methods. Given a common or ordinary definition of the term "percutaneous" as "effected or performed through the skin" (Merriam-Webster Online Dictionary, Copyright © 2004 Merriam-Webster, Inc.), in the context of the claim, "non-percutaneous" appears to mean "*not* effected or performed through the skin". However, while ductal cannulation or catheterization, as described in the prior art, does not involve piercing or perforating the skin, as would a typical insertion of a needle, for example, since the cannula or catheter is inserted into and through an orifice at the surface of the skin into the lumen of a breast duct, the cannula or catheter is nonetheless inserted "through the skin". Since, as described in the instant disclosure, the cannula or catheter is actually inserted through the skin by accessing an orifice in the skin at the surface of a breast, and because the specification does not appear to support the more limited definition of the term "non-percutaneous" as meaning non-piercing or non-perforating, which is believed to be intended, the recitation of the term in claim 34 appears to introduce new matter.

At page 5 of the amendment filed June 17, 2004, Applicant has stated that support for the new claims can be found in the specification, particularly at pages 6-8 and 14-16 and in the original claims.

Applicant's remarks have been carefully considered but not found persuasive. The disclosures at pages 6-8 appear to refer to the access, diagnosis, and treatment of

breast cancer either in the breast or in the lymphatic system, as opposed to the identification of any other type of lesion confined within the breast ductal network, such as another type of cancer. For example, at page 7 (lines 19-32), the specification teaches the clinical progression of breast cancer and describes the different stages of breast cancer. In contrast to the present claims, however, the disclosure at pages 6-8 do not describe other types of lesions within the breast ductal network that might be localized using the invention. Similarly, the disclosures at pages 14-16 appear to be limited to a discussion of targeting molecules that can be used to localize breast cancer lesions within a breast ductal network without addressing targeting molecules that can be used to localize other types of lesions within the breast ductal network. Furthermore, none of the disclosures at pages 6-8 and 14-16 appear to provide a definition of the term "non-percutaneous", which is consistent with the meaning that is believed to be intended, or clearly describe the disclosed methods of cannulation or catheterization as differing from "percutaneous" methods, since as disclosed the cannula or catheter is inserted through the skin at an orifice on the surface of a breast into the lumen of a breast duct.

Therefore, the present claims appear to introduce new matter, which violates the written description requirement set forth under 35 USC § 112, first paragraph. However, these issues might be remedied if Applicant were to point to particular disclosures in the specification, including the claims, as originally filed that are believed to provide the necessary written support for the language of the new claims.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 lacks an antecedent basis in claim 33 for the recitation of "the cells". The metes and bounds of the subject matter that Applicant regards as the invention cannot be determined.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 33 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Yoshimoto et al. (*Breast Cancer Res. Treat.* **42**: 87-90, 1997) in view of US Patent No. 5,681,543 A, and Canto et al. (*Gastrointestinal Endoscopy* **44**: 1-7, 1996) (of record).

Claims 33 and 36-39 are drawn to a method of identifying the location of a lesion within a breast duct or breast ductal network comprising delivering a compound comprising a targeting molecule coupled to an identifying agent into the breast duct, allowing the compound to specifically bind a lesion within the breast duct or breast ductal network, washing the breast duct and breast ductal network with a solution to remove nonspecifically bound compound, detecting the presence of the bound compound within the breast duct or breast ductal network, and identifying the location of the lesion to which the compound is bound within the breast duct or breast ductal network.

Yoshimoto et al. teaches a method of identifying the location of a lesion within a breast duct or breast ductal network for the purpose of excising the lesion and surrounding tissue comprising delivering a compound comprising a an identifying agent into the breast duct, allowing the compound to specifically bind a lesion within the breast duct or breast ductal network, detecting the presence of the bound compound within the breast duct or breast ductal network, and identifying the location of the lesion to which

the compound is bound within the breast duct or breast ductal network by magnetic resonance imaging of the patient's torso; see the entire document.

More particularly, Yoshimoto et al. teaches a method for diagnosing a primary lesion and assessing its spread within the breast by magnetic resonance galactography comprising injecting gadolinium-DTPA directly into a discharging breast duct and performing magnetic resonance imaging (MRI) of the breast of the supine patient before and after infusion of gadolinium-DTPA by rapid intravenous injection before surgery to remove the lesion and as little of the surrounding tissue as possible and practical; see the entire document (e.g., the abstract; page 87, columns 1 and 2; and page 90, column 1). Yoshimoto et al. teaches, because planar images are acquired while the patient is supine, the methodology provides useful information to supplement that acquired using conventional methodology (e.g., mammography), particularly since when using mammography to localize lesions within the breast, it is hard to judge the exact location or spread of the lesions because the images are acquired while the breast is compressed; see, e.g., the abstract and page 87, column 1. Yoshimoto et al. teaches their methodology enables the clinician to determine the location of the lesion within the breast while the patient is supine, as the patient would be during surgery, so the images acquired may provide the surgeon with more useful information prior to conservative surgery (i.e., the resection of the lesion and as little of the surrounding tissue as possible and practically necessary) than images acquired by conventional methodology alone; see, e.g., page 87, column 1, and page 90, columns 1 and 2.

However, Yoshimoto et al. does not teach delivering a compound comprising an identifying agent coupled to a targeting agent (claim 33), wherein said targeting agent is selected from the group consisting of a protein, an antibody, an antibody fragment, a polynucleotide, a small molecule, a liposome, a ligand, a peptide, and a receptor (claim 34). Furthermore, Yoshimoto et al. does not teach washing the breast duct into which the compound is injected to remove non-specifically bound compound (claim 34).

US Patent No. 5,681,543 A ('543) teaches identifying agents coupled to targeting agents (e.g., an antibody, small molecule, or ligand that selectively targets tumor cells)

for use in identifying the location of lesions within the breast by, for example, magnetic resonance imaging; see the entire document.

More particularly, '543 teaches gadolinium-containing polymer complexes, which exhibit surprisingly high tissue specificity and, as compared to gadolinium-DTPA, are more stable and provide marked contrast enhancement of peripheral tumor tissue by nuclear magnetic imaging for a prolonged period, bringing a marked diagnostic gain; see entire document (e.g., column 8, lines 19-26 and lines 44-52). '543 teaches the gadolinium-containing polymer complexes can be covalently attached to a biomolecule or a macromolecule, which concentrates in the organ or organ part to be examined, such as an enzyme, hormone, dextran, porphyrin, bleomycin, insulin, prostaglandin, steroid hormone, amino sugar, amino acid, peptide, protein, monoclonal antibody, lectin, lipid, or liposome (column 13, lines 25-34). '543 teaches such conjugates of monoclonal antibodies specific for tumor-associated antigens are suitable for use in tumor diagnosis (column 13, lines 34-42). '543 teaches for visualization of tumors, monoclonal antibodies or their antigen-binding fragments (e.g., Fab and $F(ab')_2$), which are specific for human tumors of the breast are suitable (column 13, lines 48-57). '543 teaches that conjugates of antibodies and the gadolinium-containing polymer complexes can be produced without loss or reduction of the binding affinity and specificity of the antibody for the antigen; see, e.g., column 14, lines 25-28. '543 teaches the conjugates can be formulated as pharmaceutical agents, which are suitable for use as contrast media for nuclear magnetic resonance imaging or MRI (nuclear spin tomography); see, e.g., column 17, lines 59-62; and column 61 and 62, Example 66.

Canto et al. teaches an endoscopic procedure comprising an *in vivo* washing step before identifying the location of tumor tissue within a patient's body. The procedure for localizing tumor tissue in a patient's body comprises contacting the tissue and surrounding area with an identifying agent, allowing the identifying agent to bind to the cells of the tissue, washing off the excess of an identifying agent, and localizing the tumor tissue so identified; see entire document (e.g., page 2, paragraph bridging columns 1 and 2).

It would have been *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made to identify the location of lesions within a breast duct or breast ductal network for the purpose of conservatively excising the lesion and surrounding tissue by a process according to claims 33 and 36-39 because: (a) Yoshimoto et al. teaches the injection of gadolinium-DPTA into the breast duct to identify the location of such lesions by magnetic resonance imaging for the purposes of excising the lesions and surrounding tissue by conservative surgery; (b) '543 teaches gadolinium-containing polymer complexes, which can be used more effectively than gadolinium-DTPA; (c) '543 teaches or suggests that the targeted delivery of gadolinium using a diagnostic compound comprising a gadolinium-containing polymer complex and a targeting agent can be performed advantageously, since a targeted identifying agent targeted to lesions in the breast duct or breast ductal network concentrate in breast duct or breast ductal network and specifically bind lesions of the breast; and (d) Canto et al. teaches or suggests that washing to remove non-specific bound diagnostic agents can be performed by *in vivo* endoscopic procedures to improve the specificity of the test by reducing background noise, or the generation of non-specific, undesired signals.

One ordinarily skilled in the art at the time the invention was made would have been motivated to do so to identify the location of such lesions a breast duct by magnetic resonance imaging for the purposes of excising the lesions and surrounding tissue by conservative surgery.

15. Claims 34 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshimoto et al. (*Breast Cancer Res. Treat.* **42**: 87-90, 1997) in view of US Patent No. 5,681,543 A, US Patent No. 4,628,027 A, and Canto et al. (*Gastrointestinal Endoscopy* **44**: 1-7, 1996) (of record) as applied to claims 33 and 36-39 above, and further in view of US Patent No. 6,168,779 B1 (of record).

Claim 34 is drawn to the method of claim 33 wherein the compound is delivered by non-percutaneous cannulation or catheterization of the breast, where the term "non-percutaneous" describes cannulation or catheterization without piercing or perforating

the skin. Claim 34 is drawn to the method of claims 33 wherein the compound is delivered to more than one duct on a breast.

Yoshimoto et al., US Patent No. 6,168,779 B1, US Patent No. 4,628,027 A, and Canto et al. teach that which is set forth above.

However, none of Yoshimoto et al., US Patent No. 6,168,779 B1, US Patent No. 4,628,027 A, and Canto et al. expressly teach that the compound comprising the identifying agent coupled to a targeting agent can be delivered by non-percutaneous cannulation or catheterization of the breast without piercing or perforating the skin (claim 34); nor do any of Yoshimoto et al., US Patent No. 6,168,779 B1, US Patent No. 4,628,027 A, and Canto et al. expressly teach or suggest delivering the compound to more than one breast duct (claim 35).

US Patent No. 6,168,779 B1 ('779) teaches delivering a desired diagnostic material through one or more orifices at the surface of the breast and into the lumens of the associated breast ducts by cannulation or catheterization without piercing or perforating the skin; see entire document (e.g., column 6, lines 54-55).

In addition, '779 teaches the cytologic analysis of nipple discharge from a breast can be used diagnostically to evaluate whether breast cancer exists within the discharging duct; however, '779 teaches, because the fluid is generally collected at the surface of the nipple, the fluid is representative of the entire ductal structure and the analysis does not generally provide information on the condition of an individual duct (column 1, lines 29-42). '779 teaches, since breast cancer usually arises from a single ductal system and exists in a precancerous state for a number of years, endoscopy in and fluid collection from individual breast ducts has great diagnostic potential for identification of intermediate markers of premalignant and malignant breast cancer lesions within the breast duct and breast ductal network; see, e.g., column 1, lines 17-62. '779 teaches the diagnostic potential of such methods cannot be realized until access to each and every duct in a patient's breast can be assured (column 1, lines 43-49). To facilitate this process, '779 teaches a method for locating and labeling an orifice at the surface of a breast into the lumen of a breast duct; see the entire document (e.g., the abstract; and column 1, lines 12-16). '779 teaches, by reliably identifying each of

such orifice, all the ductal networks within the breast can be located and subsequently accessed for diagnostic purposes; see, e.g., column 1, lines 57-62; and column 2, lines 37-43. '779 teaches the introduction of suitable diagnostic materials, such as contrast medium, into the breast ducts prior to imaging for the purpose of localizing cancerous lesions of the breast duct epithelium have been previously described by others (e.g., Sartorius, *Breast Cancer Res. Treat.* **35**: 255-266, 1995); see, e.g., column 1, line 64, through column 2, line 31. Furthermore, '779 teaches saline can be instilled into the lumen of the breast duct through a catheter to wash and/or dilate the lumen, which is then aspirated through the same catheter or another cannula; and the cells contained in the aspirated saline washings may be collected, spun down, and identified by histopathological analysis; see, e.g., column 6, lines 37-65.

It would have been *prima facie* obvious to one ordinarily skilled in the art at the time of the invention to deliver the compound according to claim 34, because '779 teaches the disclosed methods comprising cannulation or catheterization of one or all of the individual breast ducts provide a means by which a desired diagnostic material can be instilled through one or more orifices at the surface of the breast and into the lumens of the associated breast ducts.

Furthermore, it would have been *prima facie* obvious to one ordinarily skilled in the art at the time of the invention to identify, access, and deliver, to more than one breast duct according to claim 35, because '779 teaches methods for identifying each of the orifices at the surface of the breast duct associated with a breast duct and suggests the importance of evaluating the presence of lesions in each individual breast duct, not only the discharging duct, since breast cancer usually arises from a single ductal system and exists in a precancerous state for a number of years.

One ordinarily skilled in the art at the time the invention was made would have been motivated to do so to identify the location of lesions in one or more breast ducts or breast ductal networks by magnetic resonance imaging for the purposes of excising the lesions and surrounding tissue by conservative surgery and otherwise clinically intervening in the course of the disease as soon as possible and as deemed appropriate following the localization of any precancerous lesions.

Furthermore, because '779 teaches aspirated saline washings of the ductal lumen may be collected for further diagnostic use, one ordinarily skilled in the art at the time the invention was made would have been motivated to wash the lumen both to remove non-specifically bound targeting agent before image acquisition and to collect cells for additional diagnostic use.

Conclusions

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
September 17, 2004

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/20/04